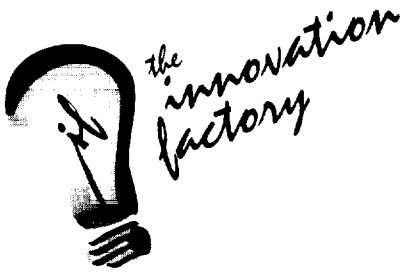

October 29, 1999

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville MD 20852

Attention: Collin L. Figueroa

RE: Docket No. 99D-2212
"Medical Devices, Draft Guidance on Quality Systems Regulation Information for Various Premarket Submissions; Availability"

Dear Mr. Figueroa,

As a developer of novel medical devices, The Innovation Factory appreciates the opportunity to comment on the August 3, 1999, *Federal Register* notice entitled "Draft Guidance on Quality Systems Regulation Information for Various Premarket Submissions."

The draft guidance appears to be a call for the inclusion of all design control procedures and a copy of the quality manual, or equivalent documentation, in future premarket approval applications (PMA) and product development protocols (PDP), and for maintaining these documents at the manufacturing facility for premarket notifications (510(k)s). According to the *Federal Register* notice this must be done "...to demonstrate that the submissions are in compliance with the revised quality system (QS) regulation."

As an initial comment on the above quote, the scope of the QS regulation reads, "The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices." (21CFR 820.1) Thus the QS regulation does not imply that submissions to the FDA need to be in compliance with it, rather that the device and the device manufacturer must be in compliance with the QS regulation. It may be misleading to require a submission to be in compliance with the QS regulation.

99D-2212

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In order to provide appropriate comments on the draft guidance, it would be helpful for us to better understand FDA's intended use of these documents. Will FDA reviewers be judging the adequacy of the design control procedures and the quality manual? Might an unfavorable review result in action against a company and its existing products? Would implementation of this guidance introduce a delay in the review process due to the reviewer needing to become familiar with the QS regulation and its implementation through various company procedures, and/or the primary reviewer passing this section on to another individual within the Agency? Some insight into FDA's expected use of newly required information may provide an area for comment.

Additionally, should this guidance become effective, we would need to know which version of a procedure should be forwarded to FDA as part of the PMA or PDP submission. For example, 820.30(b) calls for Design and Development Planning (D&DP). The D&DP procedure is used throughout the device's design and development process, which is likely to be over a period of years, especially for Class III devices. It is also likely that the D&DP procedure itself will be revisited and upgraded during that period. In this case would FDA be expecting to see the procedure that was in place at the start of the project or the one that is effective at the time of PMA submission one to four years later? Certainly the latter procedure would be more comprehensive; however, it may not exactly match with the documentation associated with the exercise of a version of the D&DP procedure that was in place at the start of the project. This type of specific guidance would be appreciated.

Thank you for the opportunity to comment on the draft guidance. We hope these remarks are useful to FDA during its review. If you need additional information or clarification of these points, please contact me at 770. 935.4404.

Sincerely,

Carolyn K. George

Carolyn K. George
Vice President, Clinical and
Regulatory Affairs

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